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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,684	02/18/2004	Mark W. Kroll	A04P1016	5251

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EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,684	KROLL, MARK W.	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/18/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-20 and 23-25, drawn to a system and method for controlling the recording of diagnostic data within an implantable device, classified in class 600, subclass 523.

   II. Claim 21, drawn to a method for controlling the recording of diagnostic data within an implantable medical device for implant within a patient, classified in class 600, subclass 515.

   III. Claim 22, drawn to a method for controlling the recording of diagnostic data within an implantable device, classified in class 600, subclass 523.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it does not require predicting a specific disorder. The subcombination has separate utility such as predicting the onset of arrhythmia.

Inventions III and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does

not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it does not require determining whether the predicted circumstances occurred and modifying the predictive parameters to improve predictive reliability. The subcombination has separate utility such as biofeedback for diagnostic purposes.

Inventions II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because does not require predicting a specific disorder. The subcombination has separate utility such as predicting the onset of arrhythmia.

3. The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such

claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Derrick Reed on 31 August 2006 a provisional election was made without traverse to prosecute the invention of group I, claims 1-20 and 23-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 21-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

6. The disclosure is objected to because of the following informalities: In paragraph 0001, line 1, "10/782,123" should be inserted immediately after "Application Serial No.", in order to reflect the updated serial number assignment. Appropriate correction is required.

Claim Objections

7. Claim 18 is objected to because of the following informalities: the claim is unclear due to grammatical mistakes (i.e., lines 2-3 of the claim). Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 12, 19-20 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker et al (U.S. 2002/0147409). Regarding claims 1-2, and 12, Baker discloses, (par. 0007) "a monitor for atrial fibrillation including a first and second momentary contact electrode sized to contact the patient. An atrial fibrillation detector circuit communicates with the first and second momentary contact electrodes and executes a stored program to receive an ECG signal from a patient touching the first and second momentary contact electrodes and detect a likelihood that the patient is experiencing atrial fibrillation. An output signal is provided to the patient if the likelihood is above a predetermined threshold." The monitor may include (par. 0013) "recording media and the atrial fibrillation detector circuit may record the received ECG signals subsequent to the patient touching the first and second momentary contact electrodes. The ECG signals may be the patient's current ECG signals or those recorded previously

during the patient's use of the device." The examiner considers this to be evaluating a likelihood that one or more circumstances will arise and controlling the recording of diagnostic data based on such evaluation. This method is performed to identified periods of time wherein there is an elevated risk of an arrhythmia, and the recording of diagnostic data is performed to record the data at least temporarily during the period of time wherein there is an elevated risk of arrhythmia.

10. Regarding clam 3, Baker discloses, (par. 0029) "an indicator light (26) is positioned on the top surface of the housing (12) to provide an indication to the patient of the condition of the patient's heartbeat. In the preferred embodiment, the indicator light shows green when no irregularities are found in the patient's heartbeat and red when atrial fibrillation is detected." The examiner considers this to be monitoring heart rate variability and identifying periods of time with reduced heart rate variability.

11. Regarding claim 19, the examiner considers the atrial fibrillation monitor to provide event records.

12. Regarding claim 20, Baker discloses, (par. 0031 and 0043) the transfer of the data from the ECG monitor via phone lines, USB ports or other recordable media. The examiner considers this to be activating the recording of diagnostic data in a temporary memory and transferring the data from the temporary memory to long-term memory if the circumstances actually occur.

13. Regarding claims 23 and 25, Baker discloses, (par. 0031) a microcontroller (36) including a non-volatile memory (38) for holding ECG signals. The examiner considers this microcontroller to be operative to evaluate the likelihood that circumstances will

arise wherein diagnostic medical data is to be recorded and to control the storage of diagnostic data in the memory based up on the evaluation. The examiner also considers this to be means for storing data, means for evaluating the likelihood that circumstances will arise wherein diagnostic medical data is to be recorded, and means for controlling the recording of diagnostic data within the means for storing based on such an evaluation.

14. Regarding claim 24, Baker discloses, (par. 0031) a "set of input/output lines is provided to the programming connector (17) such as allows programming of various parameters of operation of the atrial fibrillation monitor (10)." The examiner considers this to be an adaptive-based diagnostic controller operative to adaptively modify parameters employed by the risk-based diagnostic data controller in making its evaluation so as to improve the reliability of such evaluations.

15. Claims 1, 2, 4 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by McClure et al (U.S. 6,275,734). McClure discloses, (col. 6, lines 48-57) "processor (110) is adapted to store the broad band IEGM signal upon the occurrence of a particular event. As is understood in the art, the IEGM signal that occurs during a particular heart activity is often stored in the memory (130) so that the signal can be subsequently downloaded, via the telemetry circuit (140) to the external programmer (142), to allow a treating physician to subsequently observe the recorded cardiac event and ensure that the implanted cardiac device (100) applied the appropriate therapy for the particular patient." The examiner considers this to be evaluating the likelihood that

one or more circumstances will arise and controlling the recording of diagnostic data based upon such an evaluation.

16. Regarding claims 2 and 4, McClure discloses (col. 6, lines 38-42) a system that detects ventricular tachycardia or fibrillation.

17. Regarding claim 12, McClure discloses, (col. 8, lines 40-45) "the stored signal can be subsequently downloaded to the external programmer (142) via the telemetry circuit (140) in the manner that is well-known in the art. The actual storage process of the broad band IEGM signal is implemented by the processor (110) upon sensing the occurrence of a particular cardiac event."

18. Claims 1-2 and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al (U.S. 5,908,392). Wilson discloses, (col. 3, lines 1-6) "a system and method are provided for automatically recording and storing inter-visit medical data, where a programmable trigger initiates the recording of medical data into long-term memory, and where the medical data acquired prior to the programmable trigger are stored in long-term memory." The examiner considers this to be evaluating the likelihood that one or more circumstances will arise and controlling the recording of diagnostic data based upon such an evaluation.

19. Regarding claims 2 and 10, Wilson discloses, (col. 3, lines 28-30) "the trigger criteria define what cardiac episodes (e.g., various types of arrhythmias) and implantable device functions (e.g., automatic mode switching) the medical practitioner considers important enough to be recorded." The examiner considers this to be

identifying periods of time wherein there is an elevated risk of arrhythmia and recording the data at least temporarily during the period of time wherein there is an elevated risk of arrhythmia.

20. Regarding claim 8, Wilson discloses, (col. 4, lines 35-41) "appraising the performance of the implantable medical device and selecting a course of therapy, by providing the medical practitioner with cardiac data recorded prior to and subsequent to occurrences of cardiac episodes and implantable device functions defined by the medical practitioner as being important." The examiner considers this to be predicting the onset of an arrhythmia and activating the recording prior to the predicted onset of arrhythmia.

21. Regarding claim 9, Wilson discloses, (col. 16, lines 58-61) "a system and method are provided for recording and storing, in long-term memory and in form of data snapshots, medical data acquired prior to and subsequent to occurrence of cardiac episodes and implantable device functions defined as important by the medical practitioner." The examiner considers this to be determining whether the predicted arrhythmia actually occurred and adaptively modifying parameters employed to predict the onset of the arrhythmia based on whether arrhythmia actually occurred so as to reduce the likelihood of unnecessarily recording diagnostic data in the absence of arrhythmia.

22. Regarding claim 11, Wilson discloses, (col. 3, lines 20-23) "the memory of the implantable device of the present invention includes two temporary circular buffers--one for storing information indicative of cardiac events and another for storing cardiac

waveform samples." The examiner considers this to be examining the morphology of heart beats and predicting the onset of an arrhythmia based on detection of a significant change in morphology.

23. Regarding claims 12-13, Wilson discloses, (col. 9, lines 21-30) a "third and fourth criteria, "high atrial rate" and "high ventricular rate," trigger recording and storage of medical data when the intrinsic atrial or ventricular rate, respectively, exceeds a pre-determined amount (typically 90-200 bpm). Similarly, the fifth and sixth criteria, "low atrial rate" and "low ventricular rate" trigger the recording and storage of medical data when the intrinsic atrial or ventricular rate, respectively, fall below a pre-determined amount (typically 50 bpm)." Detecting the onset of an arrhythmia, comprising counting a number of beats occurring at a rate above a predetermined rate threshold and detecting the onset of an arrhythmia based on detection of a predetermined number of beats having a rate above the rate threshold; and activating recording upon detection of the arrhythmia.

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. Claim 5 is rejected under 35 U.S.C. 103(a) as obvious over McClure et al (U.S. 6,275,734) in view of Sweeney et al (U.S. 6,400,982). McClure discloses the claimed

invention except for identifying a time subsequent to the predicted ventricular fibrillation as a risk period. Sweeney however discloses (col. 2, lines 59-67; col. 3, lines 1-2) "an arrhythmia is predicted by: 1) detecting a conditioning event statistically associated with the occurrence of an arrhythmia in a patient's heart; 2) computing a conditional arrhythmia probability for the conditioning event from past observations of instances in which the conditioning event occurs alone or together with an arrhythmia within a specified time period; 3) computing an estimated arrhythmia probability based upon the detected occurrence of the conditioning event; and 4) predicting the occurrence of an arrhythmia within a specified prediction time period if the estimated arrhythmia probability exceeds a specified threshold value." Though Sweeney does not mention recording the diagnostic data, the invention can be used (col. 7, lines 48-51) with apparatus that include programmers and recorders. Further Sweeney and McClure both disclose diagnostic systems for use with cardiac rhythm management. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify McClure's diagnostic data recorder with Sweeney's risk period identification in order to alert the patient to periods of time when an arrhythmia is possible and analyze occurrence of arrhythmia within that time period.

26. Claims 6-7 are rejected under 35 U.S.C. 103(a) as obvious over McClure et al (U.S. 6,275,734) in view of Sweeney et al (U.S. 6,400,982) and in further view of Wilson et al (U.S. 5,908,392). For a discussion of Wilson, see below. McClure, Sweeney and Wilson all disclose diagnostic systems for use with cardiac rhythm management.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify McClure's diagnostic data recorder with Sweeney's risk period identification and with Wilson's long-term storage of diagnostic data in order to save space in the system memory.

27. Claim 14 is rejected under 35 U.S.C. 103(a) as obvious over Wilson et al (U.S. 5,908,392). Wilson discloses the claimed invention except for the number of beats within a range of one to three beats. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a range of one to three beats, since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

28. Claims 15 and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wilson et al (U.S. 5,908,392). Since the storing of the cardiac information is intended as a snapshot of a detected arrhythmia, the examiner considers it to be inherent in the system that this recording is deactivated if arrhythmia is not occurring. In the alternative, the examiner considers it to be obvious to one of ordinary skill in the art at the time of the invention to deactivate Wilson's long-term storage of diagnostic data in order to save space in the system memory.

29. Regarding claims 16-17, Wilson discloses the claimed invention but does not disclose expressly the incrementing the number of beats required to trigger activation of

the recording of diagnostic data if arrhythmia is not confirmed. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the recording of diagnostic data as taught by Wilson, with the incrementing the number of beats required to trigger recording of the data, because the applicant has not disclosed the incrementing provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with diagnostic recording system as taught by Wilson, because it allows the recording of data only associated with arrhythmia. Therefore, it would have been an obvious matter of design choice to modify Wilson to obtain the invention as specified in the claims.

Conclusion

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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